

STATEMENT BY APPLICANT

DALTON, James T.

1821

PTO/SB/08a (07-05)

Approved for use through 07/31/2008, OMB 0851-0031

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Art Unit

First Named Inventor

(use as many sheets as necessary) KUMAR, Shailendra **Examiner Name** Attorney Docket Number P-5235-US14 Sheet

Examiner	Cite	Document Number	Publication Date	DOCUMENTS Name of Patentee or	Pages, Columns, Lines, Where		
nitiels*	No.	Number-Kind Code ^{2 (Finome)}	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear		
(GOV	Α	09/935,044	08/23/2001	Dalton et al.			
	В	09/935,045	08/23/2001	Dalton et al.			
	С	09/644,970	08/2/2000	Dalton et al.			
	D	6,019,957	02/01/2000	Miller, et al.			
	E	6,071,957	06/06/2000	Miller, et al.			
	F	6, 160,011	12/12/2000	Miller, et al.			
	G.	4,636,505	01/13/ 1987	Tucker			
<u> </u>	Н	4,880,839	11/14/ 1989	Tucker	•		
	1	4, 465,507	08/14/1984	Konno, et al.			
	J	3,875,229	04/01/1975	Gold			
	K	4, 139,638	02/13/1979	Neri, et al.	,		
	L	4,191,775	03/04/1980	Glen			
	M	4, 239,776	12/16/1980	Glen, et al.			
	N	4,386,080	05/31/1983	Crossley, et al.			
	0	4, 282,218	08/04/1981	Glen, et al.			
	P	5,609,849	03/11/1997	Kung			
	Q	5, 162,504	11/10/1992	Horoszewicz			
	R	5,656,651	08/12/1997	Sovak, et al.			
	S	6,838,484	01-2005	Steiner, et al			
	r	6,569,896	05-2003	Dalton, et al			
	U	6,998,500	02-2006	Dalton, et al			

Examiner Signature	J. Kumar	Date Considered	7/30	07

Dalton, et al

04-2006

7,026,500

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Substitu	te for form 1449.	AVPTO		Complete if Known			
				Application Number	10/849,039		
INFO	RMATION	DISCLOSE	JRE	Filing Date	May 20, 2004		
STA	TEMENT E	Y APPLICA	ANT	First Named Inventor	DALTON, James T.		
				Art Unit	1621		
(tu	se as many she	ets as necessary	n	Examiner Name	KUMAR, Shallendra		
Sheet	2	of	4	Attorney Docket Number	P-5235-US14		

			FOREIGN PA	TENT DOCUM	MENTS		
Examir Initials*	· IC	ite io.	Foreign Patent Document Country Code ³ Number Kind Code ⁸ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columna, Lines, Where Relevant Passages or Relevant Figures Appear	
A CO	/ W	v	WO98/53826	12/03/1998	Dalton et al.		1
	х	ζ	EPO 100 172	02/08/1984	Tucker		乜
	Y	ľ	EP0 040 932	02/12/1981	Crossley et al.		10
	z	:	WO95/19770	07/27/1995	Gray		10
1	Ų A	AA	EP 0253503	12/11/1991	Tucker		E

		FOREIGN I	PATENT DOC	UMENTS		
Examine Initials*	Cite No.	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columna, Lines, Where Relevant Passages or Relevant Figures Appear	7.5
(g)	вв	WO 02 00617	01-03-2002	Bristol Myers Squibb		
	cc	WO 01 27622	04-19-2001	Bristol Myers Squibb		
	DD	WO 01 28990	04-26-2001	Nobex Corporation		70
	EE	WO 01 34563	05-17-2001	Nobex Corporation		1
	FF	WO 98 05962	02-12-198	Panvera Corporation		7
	GG	EP 000 2892	02-06-1985	Imperial Chemical Indust.		\top
	нн	JP 52-128329	10-27-1977	Teikoku Hormone Mfg.		\top
	II	JP 54-63047	12-16-1980	Glen, et al		\top
	13	GB 1360001	03-16-1970	Neri, et al		\top
	кк	WO 95 19770	07-25-1995	Sepracor inc.		\top
	LL	WO 02 016310	02-28-2002	Dalton, et al	·	$\dashv \dashv$
	мм	WO 98 55153	12-10-1998	Dalton, et al		\dashv
	NN	WO 03049675	06-19-2003	GTX Inc.		+
4	00	WO 03065992	08-14-2003	GTX Inc.		+

Examiner	J. Kumar	Date	7	120	7
Signature	0 , 0	Considered	') "	1 ' '

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Substitu	ite for form 144	9B/PTO		Complete if Known			
				Application Number	10/849,039		
INFO	RMATION	I DISCLO	SURE	Filing Date	May 20, 2004		
STAT	EMENT	BY APPLI	CANT	First Named Inventor	DALTON, James T.		
				Art Unit	1621		
(use as many sheets as necessary)			sary)	Examiner Name	KUMAR, Shallendra		
Sheet	3	of	4	Attorney Docket Number	P-5236-US14		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cîle No.	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(e), publisher, city and/or country where published.	T²
& .	Howard Tucker and Glynne J. Chesterson, J. Med Chem. 1988, 31, pp. 885-887, "Rethe Nonsteroidal Antiandrogen - 4'-Cyano-3-{(4-fluorophenyl)sulfonyl}-2-hydroxy-3'-(trifluoromethyl)-propionanilide and the Determination of the Absolute Configura Active Enantiomer "		
	QQ	D. McKillop, et al., "Enantioselective motabolism and pharmacokinetics of Casodex in the male rat", Xenobiotica, 1995, Vol. 25, No. 6, 623-634.	
	RR	Leonid Kirkovsky, et al., "[125]-Radionated Bicalutamide Analogs as Potential Imaging Agents for Prostate Cancer", Poster Presentation MEDI 155, 214th ACS National Meeting, Las Vegas, NV, Sept. 7-11, 1997, Department of Pharmaceutical Sciences, University of Tennessee, Memphis, TN 38163	<u>.</u> .
	SS	David T. Baird and Anna F. Glasier, "Hormonal Contraception - Drug Therapy", The New England Journal of Medicine, May 27, 1993, pp. 1543 - 1549	<u> </u>
	П	F.C. W. Wu, "Male Contraception: Current Status and Future Prospects", Clinical Endocrinology, (1988), 29, pp. 443-465	
	บบ	Carl Djerassi and S.P. Leibo, "A new look at male contraception", Nature, Vol. 370, pp. 11-12	
	vv	World Health Organisation Task Force on Methods for the Regulation of Male Fertility, "Contraceptive efficacy of testosterone-induced azoosperinia in normal men", The Lancet, Vol. 336, October 20, 1990, pp. 955-959and 1517-1518	
	ww	C. G. Francisco, et al., "Long-acting contraceptive agents: testosterone esters of unsaturated acids", Steroids, January 1990, vol. 55, Butterworths	
	xx.	John M. Hoberman and Charles E. Yesalis, "The History of Synthetic Testesterone", Scientific American, February 1995, pp. 76-81.	
	YY	Leonid Kirkovsky, et al., "Approaches to Irreversible non-steroidal chiral antiandrogens", Department of Pharmaceutical Sciences, University of Tennessee, 47th Southeast/51st Southwest Joint Regional Meeting of the American Chemical Society, Memphis, TN, Nov. 29-Dec. 1, 1995	
4	zz	David J. Handelsman, "Bridging the gender gap in contraception: another hurdle cleared" The Medical Journal of Australia, Vol. 154, February 18, 1996, pp. 230-233.	

Examiner		Date	7)20 00
Signature	1 3. pun	Considered	1/0/0/0/

EXAMINER: Initial if reference considered, whether or not challon is in conformance with MPEP 609. Draw tine through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

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Substil	tute for form 144	эв/РТО		Complete if Known			
				Application Number	10/849,039		
INFO	RMATION	DISCLOS	SURE	Filing Date	May 20, 2004		
STA	TEMENT E	Y APPLIC	CANT	First Named Inventor	DALTON, James T.		
				Art Unit	1621		
(U	se as many she	ets as necess	ary)	Examiner Name	KUMAR, Shailendra		
Sheet	4	of	4	Attorney Docket Number	P-5235-US14		

	· · · · ·	NON PATENT LITERATURE DOCUMENTS	
Examiner niliais*	Cite No.'	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ,
8	a	Edwards JP, Higuchi RI, Winn DT, Pooley CLF, Caferro TR, Hamann LG, Zhi L, Marschke KB, Goldman MB, and Jones TK. Nonsteroidal androgen receptor agonists based on 4-(trifluoromethyl)-2H-pyrano[3,2-g]quinolin-2-one. Bioorg. Med. Chem. Lett., 9: 1003, 1999.	
	ь .	Zhi L, Tegley CM, Marschke KB, and Jones TK. Switching androgen receptor antagonists to agonists by modifying C-ring substituents on piperidino[3,2-g]quinolone. Bioorg. Mcd. Chem. Lett., 9: 1009, 1999.	
	С	Higuchi RI, Edwards JP, Caferro TR, Ringgenberg JD, Kong JW, Hamann LG, Arienti KL, Marschke KB, Davis RL, Farmer LJ, and Jones TK. 4-Alkyl- and 3,4-diaklyl-1,2,3,4-tetrahydro-8-pyridono[5,6-g]quinolines: potent, nonsteroidal androgen receptor agonists. Bioorg. Med. Chem. Lett., 9:1335,1999.	_
	d	Hamann LG, Mani NS, Davis RL, Wang XN, Marschke KB, and Jones TK. Discovery of a potent, orally active nonsteroidal androgen receptor agonist: 4-ethyl-1,2,3,4-tetrahydro-6-(trifluoromethyl)-8-pyridono[5,6-g]-quinoline (LG121071). J. Med. Chem., 42: 210, 1999.	
	e	Rosen J, Day A, Jones TK, Jones ET, Nadzan AM, and Stein RB. Intracellular receptors and signal transducers and activators of transcription superfamilies: novel targets for small-molecule drug discovery. J. Med. Chem., 38: 4855, 1995.	
	f	Dalton JT, Mukherjee A, Zhu Z, Kirkovsky L, and Miller DD. Discovery of Nonsteroidal Androgens. Biochem. Biophys. Res. Commun.,244(1):1-4, 1998.	
	8	Edwards JP, West SJ, Pooley CLF, Marschke KB, Farmer LJ, and Jones TK. New nonsteroidal androgen receptor modulators based on 4-(trifluoromethyl)-2-(1H)-Pyrololidino[3,2-ig]quinolone. Bioorg. Med. Chem. Lett., 8: 745, 1998.	
	h	Eliason, et al "High Throughput Fluorescence Polarazation-Based Screening Assays for the Identification of Novel Nuclear Receptor Ligands." Abstracts of Papers, 223rd ACS National Meeting, Orlando Fla. U.S. 2002	
	i	Berger, et al "Concepts and Limitations in the Application of Radiolabeled antiandrogens, estrogens, or androgens as isotropic scanning agents fro the prostate." Invest. Urol. 1975 1391, 10-16	0
	j	Narayanan, et al "Steroidal Androgens and Nonsteroidal, Tissue Selective Androgen Receptor Modulators (SARM) Regulate Androgen Receptor Function Through Distinct Genomic and Non-Genomic Signaling Pathways." The Endocrine Society – Programs and Abstracts – 89th Annual Meeting – Paper P1-595.	
	k	Yepuru, et al "AN Angrogen Receptor-b Specific Selective Estrogen Receptor Modulator (SERM) Inhibits the Growth of the Prostate Cancer Cells and Stromal-Epithilial Tumor Xenograft." The Endocrine Society – Programs and Abstracts – 89th Annual Meeting – Paper OR6-3.	
4		Dalton, et al "Therapeutic Promise of Selective Androgen Receptor Modulators (SARSs): Preclinical and Clinical Proof-of-Concept Studies." The Endocrine Society – Programs and Abstracts – 89th Annual Meeting – Paper S41-2.	

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